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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/236,939	01/25/1999	PAUL J. GODOWSKI	P0854C1D4	9791

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EXAMINER

ULM, JOHN D

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 11/25/2002

28

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/236,939

Applicant(s)
Baker et al.

Examiner
John Ulm

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1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 30, 2002
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-44 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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- 1) Claims 31 to 44 are pending in the instant application.
- 2) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 July of 2002 has been entered.
- 3) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 5) Claims 31 to 44 stand rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 5 of Paper Number 11. Applicant has again traversed this rejection on the premise that the claimed isolated nucleic acid has utility in the diagnosis and treatment of breast and liver cancer. Applicant has failed, however, to identify that specific portion of the instant specification which contains a specific assertion that the presence of a protein of the instant invention in breast or liver is diagnostic for cancer. It is a matter of law that, unless a practical utility is *prima facie* obvious to one of ordinary skill, the instant specification must disclose and assert at least one specific and substantial utility for the claimed invention. The instant specification does not contain a specific assertion that the detection of a protein of the instant

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invention, or a nucleic acid encoding that protein, in a liver or breast sample is diagnostic for liver or breast cancer.

Applicant has essentially adopted the position that, because Table 3 on page 96 of the instant specification demonstrates the expression of HPTKA6 mRNA in a single cell line that derived from a breast cancer and a single cell line derived from a liver cancer but not in normal breast and liver tissue, one of ordinary skill in the art would arrive at the conclusion that this protein is diagnostic for breast and liver cancer. Applicant's position is without merit, as explained at length in section 5 of Paper Number 21, which arguments will not be repeated here. Because the gene expression patterns in cell lines are not reliably representative of the gene expression patterns of the cells from which those lines originated, for those reasons of record, one would not conclude that a protein which is expressed in a liver or breast cell line but not in liver or breast is diagnostic for cancer. One of ordinary skill in the art of molecular biology would not find Applicant's asserted diagnostic utility, which is absent from the instant specification, to inherently flow from the facts contained therein.

6) Claims 31 to 44 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

7) The rejection of claims 31 to 44 under 35 U.S.C. 102(a) as being clearly anticipated by the Johnson et al. publication (P.N.A.S. 90:5677-5681, Jun. 1993) has been reconsidered and withdrawn. Whereas this publication expressly disclosed that the protein of the

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instant invention was associated with breast cancers and demonstrated this associated in Figure 2 and 3 by showing the increased expression of mRNA encoding that protein in a **plurality** of breast cancer cell lines, it failed to discuss the expression level of that protein in normal breast tissue. Therefore, one would not have recognized that protein as being useful as a diagnostic marker.

However, for the record, Applicant is advised that, to antedate a reference, Applicant must show that they were in possession of as much of the invention as the reference. M.P.E.P. 715.04 states that:

“under 37 CFR 1.131 practice, proof of a utility must be shown only if the reference discloses a utility. In re Wilkinson, 304 F.2d 673, 134 USPQ 171 (CCPA 1962); In re Moore, 444 F.2d 572, 170 USPQ 260 (CCPA 1971).”

Had Johnson et al. disclosed that the protein described therein was expressed in a plurality of breast cancer-derived cell lines but not in normal breast tissue, this rejection would be maintained.

8) Claims 31 to 33, 35 to 38 and 40 to 44 stand rejected under 35 U.S.C. 102(a) as being clearly anticipated by the Di Marco et al. publication (J. Biol. Chem. 268:24290-24295, 15 Nov. 1993) for those reasons of record. This reference asserted that the protein described therein was expected to be a receptor for Nerve Growth Factor (NGF) and gave reasons why one would believe that this receptor, alone, was responsible for mediating the effects of NGF on keratinocytes, a process of clinical significance. Applicant has not demonstrated a knowledge of an association between HPTKA6 and NGF action on keratinocytes before the publication date of

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Di Marco et al. Therefore, this rejection is maintained because Applicant has not shown that they were in possession of as much as the reference at the time that it was published.

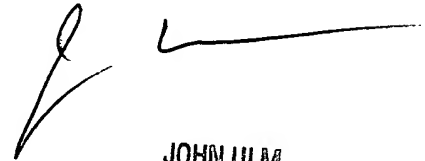
9) Applicant's arguments filed 30 July of 2002 have been fully considered but they are not persuasive for those reasons given above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800